

June 14, 2002

Carrie Hamilton
Toxicology Coordinator
Air Products and Chemicals, Inc.
7201 Hamilton Boulevard
Allentown, PA 18195

Dear Ms. Hamilton:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 2,4,7,9-Tetramethyl-5-decyne-4,7-diol, posted on the ChemRTK HPV Challenge Program Web site on January 31, 2002. I commend Air Products and Chemicals, Inc. for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its HPV Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the attached Comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Air Products and Chemicals, Inc. advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site "Submit Technical Questions" button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Attachment

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission: 2,4,7,9-Tetramethyl-5-decyne-4,7-diol

SUMMARY OF EPA COMMENTS

The sponsor, Air Product and Chemicals, Inc., submitted a Test Plan and Robust Summaries to EPA, dated January 3, 2002, for 2,4,7,9-Tetramethyl-5-decyne-4,7-diol (CAS No. 126-86-3). EPA posted the submission on the RTK HPV Challenge Web site on January 31, 2002.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties and Environmental Fate. The submitter needs to provide method details for ready biodegradability test in the robust summary.
2. Health Effects. The submitter needs to include a robust summary and missing data for the developmental toxicity study.
3. Ecotoxicity. The submitter needs to provide method details in the robust summaries

EPA is requesting that the Sponsor advise the Agency within 60 days of any modifications to its submission.

EPA COMMENTS ON THE 2,4,7,9-Tetramethyl-5-decyne-4,7-diol CHALLENGE SUBMISSION

General

The Submitter has prepared an excellent Test Plan. Most of the submitted studies have followed OECD guidelines and GLPs. The Test Plan includes study details on each endpoint that need to be included in the robust summaries so that they meet the standards of the HPV Challenge Program.

Test Plan

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

Adequate existing data are available for these endpoints.

Fate (photodegradation, stability in water, biodegradation, and transport/distribution).

Adequate existing data are available for these endpoints. However, the submitter needs to provide method details for the biodegradation test.

Health Effects (acute toxicity, repeat dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

The submitter needs to include relevant developmental toxicity data from a single-generation reproduction toxicity study under the Developmental Toxicity section of the IUCLID Data set. Although most of the studies were conducted following the OECD guidelines and GLPs, additional essential information needs to

be included in some robust summaries (some of this information is present in the Test Plan).

Ecological Effects (fish, daphnid, and algal toxicity)

Although most of the studies were conducted following the OECD guidelines and GLPs, some relevant information and method details for each of these studies need to be included in the robust summaries.

Specific Comments on Robust Summaries

Environmental Fate.

The submitter needs to provide method details for the ready biodegradability test.

Health Effects.

Repeated-Dose Toxicity. In the rat 28-day study summary, the submitter needs to indicate whether organ weights and histopathology data were collected.

Developmental Toxicity. In the robust summary of one-generation reproductive toxicity, the submitter needs to provide information on litter size, litter weight, number of corpora lutea, and number of implantations and also include this summary under Section 5.9, Developmental Toxicity.

Ecotoxicity.

Fish. In both study summaries the submitter needs to include dose levels and other method details including test conditions to allow judgement of their validity.

Daphnids. For the 2000 study (Ref. 10), the submitter needs to include dose levels and other method details including test conditions.

Algae. The submitter needs to include method details and test conditions.

Followup Activity

EPA requests that the Sponsor advise the Agency within 60 days of any modifications to its submission.